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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/677,752	10/03/00	JACKSON	W 7969-087

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HM22/0601

EXAMINER

FORD, V

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 06/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1. File Copy

Office Action Summary	Application No.	Applicant(s)
	09/677,752	JACKSON, W. JAMES
	Examiner Vanessa L. Ford	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 April 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-7, 15-24, 31, 32, 41 and 57-59 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-7, 15-24, 31, 32, 41 and 57-59 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> .	20) <input type="checkbox"/> Other: _____

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 1-7, 15-24, 31-32, 41 and 57-59 in Paper No. 5 filed on April 25, 2001, is acknowledged. Groups II-XXIX are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Declaration Defective

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: The full name of each inventor has not been set forth. The first name of the inventor has an initial.

Drawings

3. The drawings are objected to by the Draftsman under 37 CFR 1.84 or 1.152. See the attached form PTO 748.

Information Disclosure Statement

4. The information disclosure statement filed February 7, 2001 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. Only the U.S. Patent Documents and the

Foreign Patent Documents were considered. All other references were not considered because a copy was not provided for consideration.

5. The information disclosure statement is objected to because line AK has a worldwide web address cited as a reference. The worldwide web address can be readily changed and therefore, may not be available to the public.

Specification Objections

6. The specification is objected because of the use of worldwide web addresses on page 12, line 29, page 13, lines 12 and 18 and page 14, line 27. The worldwide web address can be readily changed and therefore, may not be available to the public.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-7, 15-24, 31-32, 41 and 57-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification discloses SEQ ID NO: 2 or 4 which corresponds to the amino acid sequence that encodes a PMPE or PMPI polypeptide. Claims 1-7 are directed to

sequences that are substantially homologous to SEQ ID NO: 2 or 4, corresponding sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a variant degree of identity (similarity, homology), and so forth. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO:2 or 4, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptide regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Therefore, only SEQ ID NO: 2 or 4 but not the full breadth of the claim (or none of the sequences encompassed by the claim) meets the written description provision of

35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

8. Claims 15-24, 31-32 and 41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ.ID.NO 2 or 4, does not reasonably provide enablement for a vaccine composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 15-24, 31-32 and 41 are drawn to a vaccine comprising the PMPE or PMPI polypeptide of claim 1 comprising a pharmaceutically acceptable carrier or diluent.

The specification is enabling only for claims limited to the polypeptide sequences that have been isolated, as disclosed in the specification. Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Despite the knowledge in the art for the isolation and the purification of proteins and the incorporation by reference the methods of producing vaccines, the specification

fails to provide guidance regarding how to produce a vaccine comprising the isolated polypeptide. It is unpredictable as to whether the disclosed sequences can be used to formulate the claimed vaccine using the isolated polypeptide of SEQ ID NO: 2. The specification does not provide working examples to provide adequate guidance as to which vaccine formulations are being claimed. One of skill in the art would require guidance, in order to make or use the vaccine in a manner reasonable in correlation with the scope of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-7, 15-24, 31-32, 41 and 57-59 are being indefinite because the abbreviation PMPE and PMPI are used. The proper name of the proteins "putative membrane proteins" should be used at the first occurrence of these terms in the claims or specification.
10. Claim 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Claim 4 recites the term "substantially". It is unclear as to what the applicant is referring? Thus, the metes and bounds of "substantially" cannot be ascertained. Clarification as to the meaning of this term is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-7, are rejected under 35 U.S.C. 102(b) as anticipated by Stephens et al (*Science Volume 282, October 23, 1998, p. 754-759*).

Claims 1-7 are drawn to an isolated PMPE or PMPI polypeptide of a *Chlamydia spp* comprising an amino acid sequence of SEQ ID NO: 2 or 4, a sequence substantially homologous thereto, or an at least 8 amino acid fragment.

Stephens et al teach a protein that is 98% identical to the SEQ ID NO: 2 of the claimed invention. The amino acid sequence fragments of SEQ ID NO: 5-34 are included in the amino acid sequences of SEQ ID NO: 2 or 4. Therefore, the amino acid fragments that are associated with SEQ ID NO: 2 are included in the teachings of Stephens et al.

Stephens et al teach a total of nine genes named pmp encoding relating proteins. The gene family was located in two clusters with one gene being separate (p. 757, 2nd column, last paragraph and Figure 1A, p. 756). For each of the predicted proteins, the COOH-terminal residue was phenylalanine and some of the family contained predicted cleavable signal peptide leader sequences (PmpC, PmpD, PmpE, and Pmpl). These attributes suggest that the proteins are outer membrane proteins. Each was a different

size and quite dissimilar in sequence (9 to 42 % amino acid identity), but all were found to be related and shared tetrapeptide repeat motifs organized in the NH₂-terminal half of the protein (p. 757, 3rd column, 1st paragraph and Figure 1B, p. 756).

12. Claims 15-24, 31-32 and 41 are rejected under 35 U.S.C. 102(a) as anticipated by Probst et al (*WO 00/34483, published June 15, 2000*).

Claims 15-24, 31-32 and 41 are drawn to a vaccine comprising the PMPE or PMPI polypeptide of claim 1 and a pharmaceutically acceptable carrier or diluent.

Probst et al teach compounds and methods for the diagnosis and treatment of Chlamydial infection (see abstract). Probst et al also disclose pharmaceutical compositions and vaccines comprising polypeptides, antibodies and DNA sequences. Pharmaceutical compositions may comprise one or more of the above compounds and a physiological acceptable carrier. Vaccines may comprise one or more of the above compounds and an immunostimulant. Examples of the immunostimulants include adjuvants, biodegradable microspheres and liposomes (preferred immunostimulants are disclosed on p.47-49). Pharmaceutical compositions and vaccines may contain other compounds which may be biologically active or inactive. For example, one or more immunogenic portions of other *Chlamydial* antigens may be present, either incorporated into a fusion protein polypeptide or as a separate compound within the composition or vaccine (p. 45, last paragraph and p. 46, 1st paragraph).

13. Claims 57-59 are rejected under 35 U.S.C. 102(a) as anticipated by Probst et al (*WO 00/34483, published June 15, 2000*).

Claims 57-59 are drawn to an isolated recombinant PMPE or PMPI polypeptide produced by a method of culturing the transformed host under conditions suitable for expression and recovery of the PMPE and PMPI polypeptide.

Probst et al teach polynucleotides that encode a polypeptide or portion thereof (such as a portion encoding at least 15 amino acid residues of a *Chlamydial* protein), expression vectors comprising such polynucleotides and host cells transformed with such expression vectors (p. 37-42).

Since the Office does not have the facilities for examining and comparing applicant's polypeptide with the polypeptide of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the polypeptide of the prior art does not possess the same material structural and functional characteristics of the claimed polypeptide). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

The sequence comparison of the claimed invention and that of the prior art is attached.

Status of Claims

14. No claims are allowed.

Conclusion

15. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

VLF
Vanessa L. Ford
Biotechnology Patent Examiner
May 24, 2001

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